

30. (Original) The method as claimed in claim 29, wherein the waterleaf leaves extract comprises at least one compound selected from the group consisting of protein, minerals, fiber, ash, lipids, pectin, vitamin C, vitamin E, Beta-carotene, and anti-oxidants.

31. (Currently Amended) The method as claimed in claim 4 ~~or 13~~, wherein said food composition is fed to said animal for at least five weeks.

### **REMARKS**

Reconsideration and allowance of the above-referenced application is respectfully requested.

Claims 4-12, 25-27, and 29-31 are currently pending in the present application. Claims 1-3, 13-24, and 28 are withdrawn pursuant to a restriction requirement by the Examiner. Claim 31 has been amended to conform to the previous restriction requirement under which Claim 13 of non-elected Group III was withdrawn. The amendment does not substantively change or modify the application. Support for the amendment is fully provided in the application and claims as originally filed. No new matter has been added.

The Applicants herein submit a petition and amendment to correct inventorship to add an inventor to the application. Concerning the rejections under 35 U.S.C. § 112, second paragraph, the Applicants explain and clarify the “full bloom” terminology used in the specification and claims. The Applicants submit that if the *Ezekwe et al.* reference is removed as Applicants request, the rejections under 35 U.S.C. § 102(a) are overcome and the recited claims are not anticipated by *Ezekwe et al.* The Applicants further submit that if the *Ezekwe et al.* reference is removed as Applicants request, the rejections under 35 U.S.C. § 103(a) are overcome and the claims of the Applicants’ invention are not obvious or unpatentable over the combination of the

reference *Ezekwe et al.* and the Internet website reference <http://www.news.wisc.edu/3358.html> or over the Internet website reference alone. No new matter has been added in this Amendment and Response. Withdrawal of the rejections is respectfully requested.

### **Rejections under 35 U.S.C. § 112, Second Paragraph**

Claims 4-12, 25-27, and 29-31 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention, whereby the recitation “full bloom” in claims 4 and 29 is determined to be indefinite because it is not clear what is encompassed by the recitation and clarification is needed.

While Applicants are of the opinion that independent claims 4 and 29, and therefore also the dependent claims 5-12, 25-29, and 30-31 are in fact definite, Applicants wish to clarify and explain that, as generally accepted and commonly used terminology in the art, “full bloom” refers to the point in time that two-thirds or more of the plant is in bloom such that two-thirds of the flowers of the plant have fully opened or bloomed. More specifically, it is a specific stage in the reproductive and growth cycle of the plant when the nutrient content of the vegetable parts, or leaves, is maximized. Prior to or after this stage, maximum benefits from the nutrient content to an animal from ingestion are lessened or compromised.

The term “full bloom” is recited and/or described in the specification on page 1, line 15; page 3, line 22; page 5, lines 22 and 29; page 8, lines 7-10 and 18-19; and in the abstract on page 19, line 4. Applicants respectfully submit that if the Examiner determines that a definition of “full bloom” should be included in the specification and/or the claims, such can be included

without adding new matter to the application and so that the requirements of 35 U.S.C. § 112, second paragraph, are satisfied.

Accordingly Applicants respectfully submit that, based on the explanations and clarification herein, the claims recited satisfy the requirements under 35 U.S.C. § 112, second paragraph. In view of the explanations and accompanying remarks, Applicants respectfully request that the present rejections be withdrawn and Claims 4-12, 25-27, and 29-31 be determined to be allowable.

### **Rejections under 35 U.S.C. § 102**

Claims 4-9, 25-26, and 29-31 are rejected under 35 U.S.C. § 102(a) as being anticipated by *Ezekwe et al.* ("Beneficial Influence of Purslane and Waterleaf Supplementation on Cardiovascular Disease Risk in Humans," FASEB Journal, March 20, 2002, Vol. 16, No. 4, pp. A639). Applicants respectfully traverse the rejections.

Applicants respectfully assert that, if their petition and amendment to correct inventorship is granted, the above-recited rejections are overcome. Through the Petition, Statement of Edith I. Ezekwe, new Declaration, and written consent of the assignee, Applicants submit that the requirements of 35 U.S.C. § 116, third paragraph, have also been met. *In re Searles*, 422 F.2d 431, 164 USPQ 623 (CCPA 1970). Through error, Edith I. Ezekwe was not originally named in the application. Such error arose without any deceptive intention on her part or any other individual's part. The Applicants therefore petition to amend the application and correct inventorship by adding Edith I. Ezekwe, coauthor of the *Ezekwe et al.* publication, as an inventor to the application.

If the Petition is granted as the Applicants request, the listing of coauthors of the *Ezekwe et al.* publication will be exactly the same as the listing of inventors in the application for patent. Therefore, the authorship of the publication will not differ in any way from the inventive entity of the invention. Applicants submit that the rejections are therefore overcome and respectfully request that the *Ezekwe et al.* publication cited against the application be removed as a reference and as the basis for the rejections under 35 U.S.C. § 102(a). Applicants submit that a *prima facie* case of anticipation has therefore not been established since no reference exists that teaches or enables each of the claimed elements of the present invention, arranged as in the claims, either expressly or inherently as interpreted by one of ordinary skill in the art.

Applicants respectfully submit that the recited claims are therefore not anticipated by *Ezekwe et al.* Withdrawal of the rejections is respectfully requested.

### **Rejections under 35 U.S.C. § 103**

Claims 4-12, 25-27, and 29-31 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Ezekwe et al.* ("Beneficial Influence of Purslane and Waterleaf Supplementation on Cardiovascular Disease Risk in Humans," FASEB Journal, March 20, 2002, Vol. 16, No. 4, pp. A639) and Internet website <http://www.news.wisc.edu/3358.html>. Applicants respectfully traverse the rejections.

Applicants submit that their arguments herein regarding the rejections under 35 U.S.C. § 102(a) apply equally to the obviousness rejections under 35 U.S.C. § 103(a). Assuming that the Applicants' petition and amendment to correct inventorship is granted, Applicants request that the *Ezekwe et al.* publication cited as a reference in the obviousness rejections under 35 U.S.C. § 103(a) also be removed as a reference and as the basis for the rejections under 35 U.S.C. §

103(a) so that the rejections are overcome. Assuming this reference is removed, the combination of those references, and particularly the Internet website reference alone, cannot teach or suggest all the claim limitations of the invention and cannot suggest the combination or modification of the references which would be sufficient to make the present invention obvious to one of ordinary skill in the art. Moreover, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on the Applicants' disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

If the Internet website reference is used as a prior art reference by itself, Applicants respectfully traverse the rejections. Every element of the claimed invention is not present in the Internet website reference. Moreover, a multitude of differences and distinctions exist between the claimed invention and the Internet website reference as discussed herein. The reference does not teach or suggest modification to be sufficient to make the claimed invention or the claims thereof obvious to one of ordinary skill in the art. The reference likewise does not disclose the required elements or all the claim limitations of the methods of the present invention of reducing total plasma cholesterol and plasma LDL-cholesterol, while maintaining normal plasma triglyceride levels, and of increasing blood hematocrit and plasma HDL-cholesterol levels in humans and animals. Additionally, the reference does not disclose such methods of increasing beneficial cholesterol and decreasing harmful cholesterol using natural components of waterleaf.

The Internet website reference is a June 17, 1998, article involving a research study of swine (pigs) conducted by scientists at the University of Wisconsin-Madison (UWM) to assist in subsequently and ultimately learning more about coronary artery disease and associated high blood cholesterol levels in humans. The study and resultant article focuses on identification of a genetic condition that causes hypercholesterolemia in swine and centers on what the UMW

scientists believe contributes to or causes elevated blood cholesterol levels in the swine. It concerns searching for or finding genetic causes or reasons for such high cholesterol levels and coronary heart disease in swine. The research discloses the scientists' theories of how genetic mutations may influence blood cholesterol levels and coronary heart disease in swine and subsequently attempting to understanding possible genetic causes of or reasons for human coronary heart disease.

The Internet website reference cited only discusses and involves theories of genetic causes of elevated cholesterol levels and coronary heart disease. The reference does not disclose, discuss, or suggest any of the claims or the concepts of the methods of the present invention of increasing beneficial cholesterol or of reducing harmful cholesterol in humans and meat animals. Moreover, the reference does not disclose, discuss, or suggest any of the methodologies of the present invention of cholesterol modification that utilize natural components of waterleaf or any other composition, natural or otherwise.

The reference discusses the fact that the condition of high blood cholesterol levels in swine is similar to humans, the theories and problems of which are not new. It discloses identification and sequencing of genes and mutations thereof in swine that result in high blood cholesterol levels and extremely narrowed coronary arteries. In complete contrast, the present invention does not involve genetic-level studies of causes of high blood cholesterol levels and coronary heart disease. The present invention shows for the first time beneficial methods of blood cholesterol modifications and reduction of cardiovascular disease risks in humans as well as in animals, thereby improving meat quality in meat animals for human consumption, based upon similarities in biology, lipid metabolism, and digestive systems of such animals and

humans. The present invention uses waterleaf and waterleaf extract identified by the invention as having unique characteristics.

The methods and claims of the present invention reduce total plasma cholesterol and plasma LDL-cholesterol (harmful cholesterol), maintain normal levels of plasma triglycerides, and increase blood hematocrit and plasma HDL-cholesterol (beneficial cholesterol) in the blood. Additionally, the present invention utilizing waterleaf provides nutritionally-important n-3 fatty acids, antioxidants, vitamins, minerals, and soluble fiber that contribute to the total positive biological effect on health. Finally, the present invention utilizes nonpharmological means to reduce harmful cholesterol while increasing beneficial cholesterol and hematocrit by using waterleaf, which also functions as a beneficial food for human and animal health and as a vegetable having exceptional nutritional qualities. The protein content of waterleaf is an additional advantage of the present invention but not necessarily a basis for waterleaf's ability to lower blood lipids. In contrast, the Internet website reference does not involve or suggest use of any method or means to address or treat the genetic characteristic of high blood cholesterol or to beneficially modify cholesterol levels, reduce risks of cardiovascular disease, or improve human or animal health. Moreover, the reference does not involve or suggest use of waterleaf for such purposes.

The Internet website reference lacks essential elements of the present invention. It fails to teach or disclose any solution or method of reducing harmful blood cholesterol or increasing beneficial blood cholesterol to improve health. The reference disclosure of possible genetic causes of high blood cholesterol levels cannot be modified to render the claims of beneficial blood cholesterol modification of the present invention obvious. It likewise fails to suggest or to teach the use of waterleaf to obtain the results of the present invention. No suggestion exists in

the Internet website reference that waterleaf may be used to reduce harmful cholesterol and to increase beneficial cholesterol in the blood. When a reference is silent on an element of a claimed invention, it is improper to assume that the element exists or would be suggested.

Applicants submit that one of ordinary skill in the art would not have been motivated at the time of the Applicants' invention to use the teachings of the Internet website reference to utilize waterleaf or waterleaf extract to reduce harmful blood cholesterol or increase beneficial blood cholesterol in humans and animals. Further, one of ordinary skill in the art would not have considered the Applicants' invention obvious in view of the genetic-based research and identification of gene mutations that were believed to cause high levels of cholesterol in swine as disclosed in the Internet website reference. The methods of cholesterol modification involved in independent claims 4 and 29 and all dependent claims of the present invention are not at all similar or equivalent to the Internet reference disclosure. The reference does not include all of the claimed steps of the Applicants' invention and fails to provide a teaching to combine or a likelihood of success of such a combination that is required to show obviousness of the present invention.

Further, in determining obviousness, a prior art reference must be considered in its entirety. *In re Evanega*, 4 USPQ2d 1249 (Fed. Cir. 1987). When the entire teachings of the Internet reference are considered, it may be seen that the disclosure in fact teaches away from the present invention. The reference disclosure teaches what genetic causes may exist for high levels of cholesterol in swine, while the present invention discloses methods involving solutions for cholesterol-related health problems in humans and animals. The Internet reference does not teach or suggest the claims of the present invention.



Applicants submit that the Internet website reference concerning theories of genetic reasons or causes of high cholesterol levels in swine do not and cannot teach or suggest a modification of the reference to appear to be sufficient to make the present invention and the claims thereof involving methods of reducing undesirable blood cholesterol levels and increasing desirable blood cholesterol levels in humans and animals, and their associated positive effects of reducing risks of cardiovascular and coronary heart diseases in humans and meat animals that humans consume, obvious to one of ordinary skill in the art at the time of the Applicants' invention.

The Internet reference cited does not include all of the claimed steps of the present invention and does not teach or suggest the present invention as claimed. Applicants submit that the rejections are overcome and respectfully request that the *Ezekwe et al.* publication and the Internet website reference cited against the application be removed as a reference and as a basis for the rejections under 35 U.S.C. § 103(a). Applicants submit that a *prima facie* case of obviousness has therefore not been established since no reference or combination of references exists that was available to the inventors and that teaches a suggestion to combine or to modify the reference(s) so that such a combination or modification would appear to be sufficient to have made the claimed present invention obvious to one of ordinary skill in the art.

Applicants respectfully submit that the claims of the present invention are not obvious or unpatentable over *Ezekwe et al.* and the Internet website reference. Accordingly, withdrawal of the rejections is respectfully requested.

The Applicants submit that the above amendment and remarks address and overcome all rejections of the Examiner. Withdrawal of the rejections and allowance of the claims and amendment are respectfully requested.

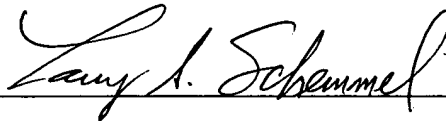
### CONCLUSION

In light of the above, the Applicants believe and respectfully assert that this application is now in condition for allowance and therefore request favorable consideration.

If any points remain in issue which the Examiner feels may be best resolved through a personal or telephonic interview, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

Respectfully submitted,

OFFICE OF THE ATTORNEY GENERAL  
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A handwritten signature in cursive script, reading "Larry A. Schemmel", is written over a horizontal line.

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